United States Court of Appeals for the Federal Circuit

01-1098

GENENTECH, INC.,

Plaintiff-Appellant,

v.

AMGEN, INC.,

Defendant-Appellee.

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Appealed from: U.S. District Court for the Northern District of California

Judge William H. Alsup

United States Court of Appeals for the Federal Circuit

01-1098

GENENTECH, INC.,

Plaintiff-Appellant,

v.

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DECIDED: April 29, 2002

Before MICHEL, RADER, and SCHALL, Circuit Judges.

RADER, Circuit Judge.

On summary judgment, the U.S. District Court for the Northern District of California determined that Amgen, Inc. (Amgen) did not literally infringe Genentech, Inc.'s (Genentech's) U.S. Patent Nos. 4,704,362 (the '362 patent), 5,221,619 (the '619 patent), and 5,583,013 (the '013 patent). Genentech, Inc. v. Amgen, Inc., No. C 96-03752 WHA, slip op. at 1-2 (N.D. Cal. Oct. 12, 2000) (Amended Summary Judgment Order). The district court also barred Genentech from proceeding on a theory of infringement under the doctrine of equivalents. Id. Because the district court did not abuse its discretion, this court affirms the district court's decision to preclude Genentech from asserting infringement under the doctrine of equivalents. The district court, however, relied on an erroneous claim construction in granting Amgen's motion for

summary judgment. Accordingly, this court vacates and remands for a determination of infringement under this court's revised claim construction.

I.

Genentech owns the '362, '619 and '013 patents. These patents claim methods and cloning vehicles for the introduction and expression of genetic information, i.e., deoxyribonucleic acid (DNA) or genes, in unicellular organisms that do not naturally contain or express that genetic information. The patents thus enable introduction of a DNA sequence, such as a synthetic gene that expresses a usable protein, into cells via a cloning vehicle. The cells then express this sequence through the endogenous protein-making machinery of the cell. The inventions thus enable harvesting valuable proteins from single cell "factories."

Inside a bacterial cell, the expression of a gene into a protein involves a two-step process. First, the cell transcribes the DNA sequence into messenger ribonucleic acid (mRNA) by an enzyme called RNA polymerase. The RNA polymerase then binds to a specific sequence within the DNA known as a "promoter" upstream from the DNA sequence encoding the usable protein. To control transcription, and therefore protein expression, the DNA sequence upstream from the usable gene also contains a site called an "operator." The operator controls transcription by binding a protein known as a "repressor." When the repressor binds to the operator, the repressor prevents the RNA polymerase from binding to the promoter, and therefore blocks transcription.

After transcribing a DNA sequence into mRNA, the cell engages in the second step, translation of the mRNA into protein. Specifically, a ribosome, which is a cellular structure involved in converting mRNA to polypeptides, binds to an upstream portion of

the mRNA sequence known as the "ribosome binding site." This binding triggers translation of the mRNA into a linear chain of amino acids -- a protein.

The three patents at issue, which contain nearly identical specifications, describe the use of a recombinant cloning vehicle (e.g., a plasmid, comprising a circular piece of non-chromosomal double-stranded DNA) to transform a unicellular organism host such as the bacterium E. coli to enable that organism to make large amounts of a protein that it would not otherwise produce. The first claim in all three patents sets forth the invention:

> '362 claim 1:
> A recombinant DNA cloning vehicle suited for transformation of a microbial host comprising
> (a) a homologous control region which regulates expression of a structural gene and
> (b) a DNA insert comprising . . . in that the DNA insert is . . . and the host transformed thereby is capable of expressing . . . under the control of the said control region and in recoverable form.
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> '619 claim 1:
> A process for the production of a polypeptide comprising a preselected functional mammalian polypeptide or polypeptide intermediate therefor in a microbial cell culture, said process comprising
> I. effecting expression of said polypeptide in a microorganism transformed with a replicable cloning vehicle comprising DNA encoding said polypeptide which DNA is under the control of an expression control region homologous to said microorganism; and
> (ii) recovering the polypeptide from said cell culture.
>
> '013 claim 1:
> A process for the production of a polypeptide comprising . . . effecting expression of said polypeptide in a microorganism transformed with a replicable cloning vehicle comprising DNA encoding said polypeptide which DNA is under the operative control of an expression control region functional in E. coli comprising operatively linked promoter, operator and ribosome binding site DNA.

(Emphasis added.)

In its 17 May 1999 claim construction order, the district court (Judge Smith) construed the relevant terms in the claims. Genentech, Inc. v. Amgen, Inc., No. C96-3752 FMS, slip op. at 1 (N.D. Cal. May 17, 1999) (Order). The district court determined that the "control region," which regulates gene expression, contains at least three control elements: a promoter, an operator, and a ribosome binding site. Id. at 24. As construed by the district court, the "control region" in all three patents must be taken from a single "operon" (i.e., DNA comprising a control region and the gene whose expression is regulated by that control region).[1] Id. at 20-23. Variation from the native control region of the untransformed host is permissible as long as the control region remains operable, i.e., the control region need not be intact. Id. at 20.

The court construed "homologous" in the '362 and '619 patents to mean that the control region DNA sequence is taken from, and ordinarily is endogenous to, the host DNA in its untransformed state. Id. at 12. To be endogenous to the host, DNA must be either part of the chromosomal host DNA, part of the plasmid DNA native to the host, or part of the chromosomal or plasmid DNA native to a "bacteriophage" (i.e., a bacterial virus from which one may derive a plasmid) ordinarily found in the bacterial host cell. Id. A control region is not homologous if it includes any alterations in the endogenous sequence, with the single exception of a promoter mutation described in the patent,

[1] Under this construction, "hybrid" control regions are outside the scope of the claims. Id. at 21. On appeal, neither party challenges this claim construction. A hybrid control region is one comprised of control elements from various operons, in which the sequence of the control elements does not correspond to the sequence found in a single operon.

namely, deletion of the catabolite activator protein (CAP) binding site. Id. at 10-12; '362 patent, col. 2, ll. 31-35.[2]

The district court construed the term "functional in E. coli" to mean that the control region performs in E. coli. Although operative in E. coli, the term does not mean that the control region must be homologous to E. coli. Id. at 15. The district court also interpreted the term "operatively linked" to mean that the promoter, operator, and ribosome binding site (P, O, and RBS) are sufficiently connected to direct and regulate expression. Id. at 34. This term does not require that the P, O, and RBS appear in any particular order.

As to the term "ribosome binding site," the district court originally construed it to mean "a DNA sequence that is an irreducible constituent of the expression control region that, when transcribed into mRNA, is bound by the ribosome, and is thus required for the initiation of translation." Id. at 50. After Judge Smith issued the 17 May 1999 claim construction order, the case was transferred to Judge Alsup. In its 12 October 2000 amended order granting Amgen's motion for partial summary judgment, the district court elaborated: "Judge Smith's requirement that the ribosome binding site be 'bound' by the ribosome is best understood to mean that the ribosome binding site consists of the entire sequence encompassed (or bound) by the two RNA sites with which the ribosome interacts to initiate translation." Amended Summary Judgment Order at 13.

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[2] In ruling on the summary judgment motion, the district court (Judge Alsup) did not address whether a "homologous control region" requires an intact control region endogenous to the host. Genentech, Inc. v. Amgen, Inc., No. C 96-03752 WHA, slip op. at 10 (N.D. Cal. Aug. 28, 2000) (Original Summary Judgment Order); Amended Summary Judgment Order at 12.

Amgen makes and sells Neupogen®, a recombinant methionyl human granulocyte colony stimulating factor (met-hGCSF) protein. This protein accelerates the replication of human white blood cells. Amgen employs E. coli to produce Neupogen® with a recombinant plasmid containing the gene for met-hGCSF. Original Summary Judgment Order, at 2. The regulatory region (P, O, and RBS) of Amgen's plasmid is derived in part from the bacteriophage lambda. The first 72 base pairs of the Amgen regulatory region are identical to the first 72 base pairs of the endogenous lambda regulatory region. These 72 base-pairs encompass the promoter and operator in both regulatory regions. Id. at 4. As noted by the district court, the RBS includes, at minimum, a Shine-Dalgarno (S-D) sequence (a conserved sequence of five nucleotides in this case) and a start codon, ATG (the first three nucleotides translated into an amino acid). Id. The ribosome binds the mRNA at these two sequences. The S-D sequence and the start codon are separated by "linker" base-pairs (usually about 10 base-pairs) that do not actually bind the ribosome. The district court found, however, that these linker base-pairs, like the S-D sequence and the start codon, are necessary for the initiation of translation. Id.

Importantly, the base-pairs linking the S-D sequence and the start codon in Amgen's plasmid are different in number and identity from the linker base-pairs in the endogenous lambda sequence:

bacteriophage lambda:	AGGAGAATCCAGATG
Amgen's plasmid:	AGGAGGTAATAAATAATG

Id. at 5.

Because the district court determined that a "control region" (P, O, and RBS) must come from a single operon, and that a "ribosome binding site" encompasses the

S-D sequence, the start site, as well as the linker base-pairs, the district court found no literal infringement. Specifically, although Amgen's P and O came from the lambda operon, a comparison of the sequences shows that Amgen's RBS (with its alternative linker sequence) did not. In granting summary judgment of no literal infringement, the district court also denied further discovery. According to the district court, Amgen's process for deriving its RBS was irrelevant because Amgen's plasmid RBS sequence did not match the RBS of lambda. Id. at 12.

Applying its local rules, the district court concluded that Genentech did not allege infringement under the doctrine of equivalents (DOE) in its complaint or in its Civil Local Rule 16-9 Claim Chart. Id. at 7. In the Northern District of California, under Civil Local Rule 16-9(a)(3), a claim chart must state "whether such infringement is claimed to be literal or under the doctrine of equivalents." Civ. L.R. 16-9(a)(3). The district court rejected the proposition that Genentech's failure to include in its chart a claim of infringement by equivalents was simply excusable oversight. Original Summary Judgment Order at 8.

Genentech appeals the district court's summary judgment of no literal infringement and its enforcement of the local rule to bar a theory of infringement under the doctrine of equivalents. This court has jurisdiction under 28 U.S.C. § 1295(a)(1) (1994).

II.

This court reviews without deference a district court's grant of summary judgment and draws all justifiable inferences in favor of the nonmovant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986); Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d

1342, 1353, 47 USPQ2d 1705, 1713 (Fed. Cir. 1998). This court also reviews claim construction without deference. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456, 46 USPQ2d 1169, 1174 (Fed. Cir. 1998) (en banc).

On procedural issues not unique to this court's exclusive jurisdiction, this court applies the procedural law of the regional circuit, in this case the United States Court of Appeals for the Ninth Circuit. Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 807, 53 UPSQ2d 1289, 1297 (Fed. Cir. 1999). The Ninth Circuit reviews a district court's denial of a motion under Fed. R. Civ. P. 56(f) for an abuse of discretion. Garrett v. City of San Francisco, 818 F.2d 1515, 1518 (9th Cir. 1987). The Ninth Circuit reviews a district court's application of local rules and decision to enforce a pretrial order's limits on theories of liability for an abuse of discretion. Acorn v. City of Phoenix, 798 F.2d 1260, 1272 (9th Cir. 1986); United States v. Warren, 601 F.2d 471, 474 (9th Cir. 1979). The Ninth Circuit reviews a district court's evidentiary rulings for an abuse of discretion. United States v. Meyers, 847 F.2d 1408, 1411 (9th Cir. 1988).

III.

Genentech argues on appeal that the term "ribosome binding site" in claim 1 of the '013 patent encompasses only the S-D sequence and the start site because they are the only sequences that bind the ribosome to initiate translation. Thus, according to Genentech, the RBS, and consequently the "control region" of claims 1 in the '362 and '619 patents, do not include the "non-functional" linking nucleotides that do not directly bind the ribosome. This assertion is important to Genentech's assertion of literal infringement because Amgen's plasmid regulatory region (P, O, and RBS) differs from the endogenous lambda regulatory region only in the RBS linker sequence. If

"ribosome binding site" includes only the S-D sequence and the start codon, then Amgen's regulatory region is homologous to the lambda regulatory region, and is potentially derived from a single operon, as required under the district court's claim construction of "homologous" and "control region."

The specification does not explicitly define "ribosome binding site." Claim 1 of the '013 patent uses the term without explanation. The specification mentions the term once when referring to the regulatory element derived from lambda DNA. '013 patent, col. 9, ll. 2-8. Figure 5A in the '362 and '013 patents refers to the "Ribosome Protected RNA," which shows the area where the ribosome protects the RNA from degradation. This "Ribosome Protected RNA" does not necessarily equate to the RBS, however, because the ribosome may protect more RNA than is actually involved in transcription initiation, such as nucleotides close to the RBS.

The prosecution history sheds some light on the meaning of RBS. As stated in an amendment submitted by the patentee to the PTO on December 16, 1986:

> Shine and Dalgarno showed that nucleotides within a ribosome binding site can form base pairs with complementary nucleotides within 16S ribosomal RNA, thereby suggesting an explanation for how ribosome binding sites participate in the initiation of translation. See for example the following publications []: [citations omitted]. These early papers, the latest of which was published almost two years before applicants' filing date, certainly demonstrate that by the time of the filing of the present application [the '362 patent, filed Nov. 5, 1979] the art was well aware of the fact that a S-D sequence was one of the necessary elements of the control region that directs the expression of structural genes.
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> * * * *
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> Both Figures [5A and 5B] clearly show the . . . AGGA . . . sequence, 8-11 nucleotides before the ATG start codon, which is the Shine-Dalgarno sequence of the lac control region. It is one of the "control elements" of the lac operon and one of the "key portion(s)" of the plasmids shown.
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> * * * *

> The quoted section [from the section entitled "Plasmid Construction Generally"] unequivocally demonstrates the presence in the specification of an explicit teaching of the ribosome binding site, which includes the S-D sequence, as a necessary element in regulating expression.

Amendment submitted to U.S. Patent and Trademark Office, U.S. Application Serial No. 06/090,979, at 11, 14, 15 (Dec. 16, 1986) (Amendment) (emphasis added).

Thus, in the prosecution history, the inventors defined the S-D sequence as a necessary element of the ribosome binding site. Id. at 11, 14. Because the ribosome binding site "includes the S-D sequence," however, the ribosome binding site clearly includes something else. The prosecution history suggests that the ATG start site also is part of the ribosome binding site. As stated by the patentee during prosecution:

> [T]he thrust of [a prior art] patent is the introduction of an alleged "hybrid" ribosome binding site in which the ATG codon is brought in with the heterolog[o]us DNA rather than being present in the homologous control region. Since "ATG" is "ATG" regardless of its origins, this is a distinction without a difference.

Id. at 18. In addition to the S-D sequence, therefore, the ribosome binding site also must include at least the start codon. The start codon binds directly to the ribosome (via complementary nucleotides within the 16S ribosome RNA), and is a "necessary element[] of the control region that directs the expression of structural genes." Id. at 11.

The patent and its prosecution history, however, do not suggest whether the ribosome binding site also encompasses the linker sequence. Moreover, extrinsic evidence, such as testimony from Amgen's expert, Dr. Alexander Johnson, and Genentech's expert, Dr. Jeffrey Ravetch, does not speak directly to this issue. In his declaration submitted to the district court, Dr. Johnson states:

> In bacteria, ribosomes differentiate by initially binding with specific sequences, up to six nucleotides long, located upstream from the initiation codon, and then through a complex reaction, interact with the start codon

> to initiate translation. Collectively, these regions of nucleotides are known as the "ribosome binding site" and include all sequences necessary to initiate translation.

Johnson Decl., ¶ 32. Although Dr. Johnson appears to suggest that the S-D sequence and the start codon "are known as the 'ribosome binding site,'" he also asserts that the RBS "include[s] all sequences necessary to initiate translation." Thus, Dr. Johnson's declaration leaves open the question of whether the linker sequences might be among those necessary to initiate translation. Dr. Ravetch, on the other hand, expressly states in a declaration: "There are two components which make up the ribosome binding site: the Shine Dalgarno sequence and the initiation codon ATG. . . . A ribosome binding site is a sequence of DNA that when transcribed into RNA is capable of binding a ribosome and initiating translation." Ravetch Decl., ¶ 9.

In sum, the entire record -- both intrinsic and extrinsic evidence of claim meaning -- does not establish that the linker DNA sequence is a required functional element of the RBS. To the contrary, the record adequately supports the district court's original claim construction of "RBS" -- "a DNA sequence that is an irreducible constituent of the expression control region that, when transcribed into mRNA, is bound by the ribosome, and is thus required for the initiation of translation." Order at 50. The record shows that Judge Alsup's later interpretation of Judge Smith's claim construction order (requiring the RBS to include the linker DNA sequence between the S-D sequence and the start codon) is incorrect. Amended Summary Judgment Order at 13.

> While Judge Smith's construction correctly specifies that the ribosome binding site, when transcribed into mRNA, is bound by the ribosome and is required for translation, it may unintentionally suggest that a sequence that is necessary but not sufficient for the initiation of translation satisfies this claim limitation. Such an interpretation would include within the ambit of a ribosome binding site a single base pair that is bound by the ribosome and is necessary for the initiation of

> translation, irrespective of whether that base pair alone (along with the promoter and operator) can perform the desired function of initiating translation. Judge Smith doubtlessly did not intend such a result. Therefore this court clarifies Judge Smith's interpretation. The claim term "ribosome binding site" is properly construed according to its function of being bound by the ribosome and initiating translation, irrespective of whether, as a general proposition outside of this context, the linker DNA between the Shine-Dalgarno site and ATG start codon is included within the scope of the claim term. This court therefore adopts Judge Smith's original construction of "ribosome binding site" with slight modification and interprets it to mean a "DNA sequence that is an irreducible constituent of the expression control region that, when transcribed into mRNA, is bound by the ribosome and is thus necessary and sufficient to initiate translation."

With respect to the term "control region," which appears in the representative claims of all three asserted patents, the district court originally propounded the following construction:

> "a piece of DNA, containing at least a promoter, an operator, and a ribosome binding site, that is the part of the recombinant DNA cloning vehicle that directs and regulates expression of the structural gene. The control region must be taken from a single operon; it may not be constructed from control elements derived from various operons."

Id. at 24. Judge Smith further found that "DNA [comprising the control region] may be 'taken from' the listed sources: it may be physically obtained, cloned, partially chemically synthesized or totally chemically synthesized." Id. at 37-38.

Nevertheless, in his summary judgment ruling, Judge Alsup interpreted Judge Smith's claim construction to include a limitation on the method of obtaining the control region. In confirming that the definition of "ribosome binding site" necessarily includes the linker DNA, Judge Alsup stated that "were the term 'ribosome binding site' reduced to the Shine-Dalgarno sequence and the start codon ATG, it would be impossible to determine whether a ribosome binding site was derived from the same operon as the promoter and the operator, a requirement of the term 'control region.'" Amended Summary Judgment Order at 14. Judge Alsup assumed that the control region must

possess control elements that correspond to one and only one operon. Hence, Judge Alsup concluded that Amgen's ribosome binding site DNA was not physically "taken from" the bacteriophage lambda. Id.

Genentech asserts that by this language, Judge Alsup misapprehended the meaning of the claim term "control region" by requiring (1) that the method used to construct the control region use only one operon, and (2) that to prove this single operon source requirement was satisfied, the sequence of each control element must correspond to a control element found in one, and only one, operon.[3]

This court agrees with Genentech on this point.[4] The district court did not appreciate the distinction between the content (sequence) of the control region and the method by which one constructs the control region. Genentech does not argue that the patent supports an interpretation of "control region" that includes so-called hybrid control regions in which the operator, promoter, and ribosome binding site sequences do not correspond to the three control elements' sequences found in a single operon. Rather, it argues that as long as the sequence of the control elements correspond to the

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[3] Amgen responds that the district court did not limit the claims to a particular method of constructing an operon, but instead properly construed the "control region" limitation to require that the control elements be endogenous to the host cell. This court cannot accept Amgen's interpretation of the Summary Judgment Order, as Judge Alsup's rejection of Genentech's proposed construction of the term "ribosome binding site" on the basis of inability to determine from which operon the ribosome binding site was derived necessarily limits the methods by which a control region is constructed.

[4] It appears that the confusion between the sequence of the control region and the method for constructing it arose from the original claim construction's requirement that the control region "be taken from a single operon." This construction is only correct to the extent that it is understood to refer to a control region containing a sequence that corresponds to the sequence of the control elements in a single operon, so that it is not a hybrid control region.

sequence of the control elements found in a single operon, the "control region" limitation is satisfied, irrespective of whether a single operon was used to construct it.[5]

In the context of the patented invention, the term "control region" describes functional control elements involved in the production of a protein and is directed to a sequence of DNA, not a method for constructing such a sequence. Rather than requiring a limitation on the method of constructing a control region, the patent appears to preclude one. In the section titled "The Control Elements," the specification discloses using a control region comprising "control elements" derived from a bacteriophage infective for E. Coli. '362 Patent, col. 8, ll. 45-48. The specification further suggests obtaining control elements from "other operons or portions thereof." Id. at col. 8, ll. 56-60.

Likewise, the prosecution history shows that a control region may be constructed portion-by-portion. In an amendment submitted to the PTO on January 11, 1996, the patentee explained: "The specification quite clearly supports the preparation of expression control regions wherein the elements are taken from various sources, including partial or total synthesis, and operatively linked by generally well-known ligation means to provide functional, homologous expression control region as such." Amendment submitted to U.S. Patent and Trademark Office, U.S. Application Serial No. 08/434,321, at 6 (Jan. 11, 1996).

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[5] The district court (Judge Smith) rejected Amgen's contention that the control region must be intact, i.e., identical to a control region native to the untransformed host. Judge Smith found that the specification and file history in fact refuted Amgen's proposed limitation requiring the use of a single operon "taken intact" to construct the control region. Rather, she noted: "What these examples disclosed in the patent suggest is that some variation from the native control region of the untransformed host is permissible as long as the control region remains operable. In short, the control region need not be 'intact.'" Id. at 19-20.

Thus, all the control elements of a single operon need not be derived from a single operon to comprise a control region in the context of the patented invention, and the district court's contrary conclusion was in error. For purposes of satisfying the control region limitation, some control elements may be physically derived from an operon and other control elements may be chemically synthesized or physically derived from a different operon, as long as the sequence of the three control elements in the control region correspond to the sequence found in a single operon. This court thus finds error in the district court's requiring that each control element be unique, so as to make it possible to determine whether it was derived from the same operon as the other control elements. Simply put, the method by which the control region is constructed and the sources from which it is derived are inapposite, thus negating any requirement that such methods or sources be discernable from the sequence of the control elements.

Based on the foregoing definitions of the terms "ribosome binding site" and "control region," this court holds that the asserted claims require at least a promoter, operator, and a ribosome binding site that, when transcribed into mRNA, is bound by the ribosome and is necessary and sufficient for the initiation of translation. The promoter, operator, and ribosome binding site must correspond to the promoter, operator, and ribosome binding site found in a single operon; the sources and methods used to construct the control region are irrelevant. There is no dispute that Amgen's accused plasmid contains promoter and operator sequences that correspond to the sequences found in the lambda operon. The key infringement issue thus becomes whether, in the Amgen cloning vehicle and process, the sequences in the ribosome binding site area that correspond to the sequences in the lambda operon—the AGGAG

Shine-Dalgarno sequence and the ATG start codon—comprise the element of the control region that binds the ribosome and is (along with the operator and promoter) necessary and sufficient for the initiation of translation. On the basis of expert testimony, Genentech argues that these sequences are sufficient to bind the ribosome and initiate translation. For its part, Amgen asserts that these eight base pairs are not sufficient to bind the ribosome and, along with the operator and promoter, initiate translation. This dispute precludes granting summary judgment of non-infringement.[6]

Furthermore, summary judgment procedures required the district court to draw reasonable inferences in favor of Genentech, the non-movant. Viskase Corp. v. Am. Nat'l Can Co., 261 F.3d 1316, 1324, 59 USPQ2d 1823, 1828 (Fed. Cir. 2001). Accordingly, in light of the factual dispute and the erroneous claim construction, this court vacates the summary judgment and remands for a determination of infringement under the revised claim construction set forth above. Lampi Corp. v. Am. Power Prods., Inc., 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1454 (Fed. Cir. 2000).

IV.

In its Fed. R. Civ. P. 56(f) motion, Genentech sought access to the sequence of the entire control element in Amgen's plasmid, as well as the process by which Amgen constructed their control region. Genentech contended that it needed to compare the

[6] As an alternative ground for affirmance, Amgen argues that even if its accused plasmid contains a control region, it does not meet the "homologous control region" limitations of the asserted claims in the '362 and '619 patents. Aside from recasting its arguments concerning the "ribosome binding site" and "control region" limitations in a different context, Amgen essentially argues that because its plasmid differs from the lambda operon in areas other than the control elements (P, O, and RBS), its control region is not endogenous to lambda and thus not a homologous control region. This court leaves the consideration of this non-infringement argument to the district court to consider in the first instance.

entire control region of Amgen's plasmid to control elements of other known bacterial genetic material, such as lambda, to determine whether Amgen's control region corresponded to the control element of a single operon. Genentech requested laboratory notebooks, internal company memoranda, meeting minutes, test data, and notes relating to the specific components of Amgen's plasmid.

A sequence comparison of the relevant RBSs, which already are available to Genentech, is sufficient to determine whether the control region of Amgen's plasmid falls within the scope of Genentech's claimed "control region." For example, a sequence comparison of the RBSs is sufficient for one to be able to see whether Amgen's control region is "homologous" to lambda's control region. The P and O regions of Amgen's plasmid clearly are derived from lambda (the sequences are identical), but Amgen's RBS linker sequence has base pairs that diverge in number and identity from (i.e., are not homologous with) lambda's RBS. Additional discovery on this issue is not necessary to determine infringement. Consequently, the district court did not abuse its discretion when it denied Genentech's motion for discovery regarding the entire sequence of, or method of making, the control element within Amgen's plasmid.

V.

The district court precluded Genentech from proceeding on a theory of infringement under the doctrine of equivalents because Genentech did not expressly include that theory in a claim chart, as strictly required under Civil Local Rule 16-9 (Rule 16-9) at the time. Original Summary Judgment Order at 7. As noted by the district court, under Rule 16-9(c), the patentee may amend its claim chart: (1) on stipulation of

the parties; (2) upon a showing of excusable subsequent discovery of new information; or (3) upon a showing of clearly excusable neglect. Id.

Genentech claims that it understood Local Rule 16-9 to require that the patent holder prepare a claim chart listing whether the claimed infringement is "literal or under the doctrine of equivalents." In other words, Genentech asserts that it reasonably thought that it was required to choose between the two types of infringement when it filed its claim chart in October 1997. Based on this, Genentech argues that it believed in good faith that the claim chart did not constitute its final commitment to the theories of infringement that it could pursue. Genentech notes that it prepared the claim chart well before the court's claim construction in May 1999. Genentech's argument flies in the face of common sense and years of Federal Circuit precedent. Genentech must have known that it could initially assert both types of infringement. Furthermore, if it had any questions regarding the claim chart, it could have asked the court for a clarification.

Genentech does not assert any satisfactory reasons as to why it should be allowed to amend its claim chart. As noted by the district court, Genentech first explicitly alluded to the doctrine of equivalents more than a year after it filed its complaint and after the court issued its claim construction order. Rule 16-9 requires that the patentee give notice to the accused infringer of its infringement theories before the claim construction hearing. In this regard, Genentech contends that Amgen had notice of its doctrine of equivalents theory since 1997. For example, the parties made reference to "prosecution history estoppel" in a joint management statement in 1997. Moreover, Amgen acknowledged the relevance of doctrine of equivalents in its opposition to Genentech's motion to compel documents in 1998, and continued to

assert arguments regarding the doctrine of equivalents as late as January 2000. Finally, according to Genentech, Amgen suffered no prejudice from Genentech's failure to amend its claim chart.

Genentech's argument is unavailing because "[u]nlike the liberal policy for amending pleadings, the philosophy behind amending claim charts [under Rule 16-9] is decidedly conservative and designed to prevent the 'shifting sands' approach to claim construction." Atmel Corp. v. Info. Storage Devices, Inc., No. C 95-1987, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998). Furthermore, this court defers to the district court when interpreting and enforcing local rules so as not to frustrate local attempts to manage patent cases according to prescribed guidelines. In reviewing a district court's exercise of discretion, this court determines "whether (1) the decision was clearly unreasonable, arbitrary, or fanciful; (2) the decision was based on an erroneous conclusion of law; (3) the court's findings were clearly erroneous; or (4) the record contains no evidence upon which the court rationally could have based its decision." In re Cambridge Biotech Corp., 186 F.3d 1356, 1369, 51 USPQ2d 1321, 1329 (Fed. Cir. 1999). In this case, Genentech does not point to any specific legal or factual error in the district court's decision. While the record shows ample reasons for the district court to permit Genentech to amend its claim chart, our standard of review on this issue does not require reversal in the presence of reasons to permit amendments. Even a determination that the district court's ruling was erroneous does not require reversal. Only if the ruling is found to be clearly erroneous is reversal mandated. The district court's determination on this issue was not clearly erroneous. Accordingly, the district court did not abuse its discretion by enforcing the Local Rule and precluding Genentech

from asserting infringement under the doctrine of equivalents when Genentech did not include that theory in its claim chart.

CONCLUSION

This court vacates the summary judgment that Amgen does not infringe the '362, '619 and '013 patents. This court remands the case to the district court for further proceedings to determine whether Amgen infringes the '362, '619 and '013 patents. Further, this court affirms the trial court's ruling on Genentech's noncompliance with the Local Rule.

COSTS

Each party shall bear its own costs.

AFFIRMED-IN-PART, VACATED-IN-PART, and REMANDED.